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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,073	07/17/2007	Yves Claude Nicolau	ACI-0403 (13704.105012)	4203
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EXAMINER				
KIM, YUNSOO				
ART UNIT		PAPER NUMBER		
1644				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/590,073

**Applicant(s)**

NICOLAU ET AL.

**Examiner**

YUNSOO KIM

**Art Unit**

1644

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 11/5/08, 5/4/9
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 19-27 are pending.

Applicant's election of species on SEQ ID NO:5 as an amyloid peptide and palmitic acid as a modifier without traverse filed on 6/1/09 is acknowledged.

Accordingly, claims 21 and 22 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Since a prior art revealed no prior art on SEQ ID NO:5, the search has extended to include SEQ ID NO:1.

Claims 19, 20 and 23-27 read on SEP ID NO:1 as an amyloid peptide and palmitic acid as elected species are under consideration in the instant application.

2. Applicants' submission of IDS filed on 11/5/08 and 5/4/09 has been acknowledged.
3. The title of the invention is not clearly indicative of the invention to which the claims are directed. Note that the claimed invention is drawn to the method of treating Alzheimer's disease.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19, 20 and 23-27 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 20 and 24 recite "antigenic peptide" which has no antecedent basis in claim 19. Note that the independent claim 19 recites "supramolecular antigenic constructs" and "amyloid peptide". Appropriate correction is required.

Further, the term "supramolecular antigenic construct" is not well-defined. It is not clear if the antigenic peptide is meant to include only amyloid peptide or any antigenic peptides. For examining purpose, the supramolecular antigenic construct is interpreted to mean any modified (e.g. palmitoylated) antigenic peptide.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 19, 20 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing antigenicity by administering supramolecular antigenic constructs comprising an antigenic peptide with a modification, does not reasonably provide enablement for methods of treating Alzheimer's diseases comprising administering supramolecular antigenic constructs or the use of supramolecular constructs to treat disorders comprising Alzheimer's diseases, multidrug resistance in cancer cells or prion diseases.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability

in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The claimed supramolecular constructs may be used in treating disorders comprising Alzheimer's disease, multidrug resistance in cancer cells or prion diseases. Wolf-Klein et al teaches that there is no medical treatment currently available to cure or stop the progression of Alzheimer's disease (Wolf-Klein et al., *Am Journal of Hosp Palliat Care*, 2007, 24(1):77-82, abstract, in particular) despite of current pharmaceutical advances in delaying disease progression. Even though there are five FDA approved Alzheimer's drugs, they temporarily relieve some symptoms of the diseases.

Tagliavini et al. (*Journal of Virology*, 2003, vol. 77, no. 15, p. 8462-8469) teach that there is no effective therapy for prion diseases including spongiform encephalopathy and Creutzfeldt-Jacob diseases and some candidates are still being validated (abstract, discussion, in particular)

In addition, Applicants have not provided any *in vivo* working examples that the supramolecular constructs can be used in treatment for multidrug resistance in cancer cells or prion diseases.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed supramolecular constructs in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 19, 20 and 23-37 are rejected under 35. U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of supramolecular antigenic constructs wherein the antigenic construct is a SEQ ID NOS:1-6 with a modification such as palmitoylation; however, Applicant is not in possession of any supramolecular antigenic constructs comprising any unspecified amyloid peptides with modification.

The claims broadly encompass any peptide from any amyloid protein in any lengths. The specification does not provide written description for such broad genus peptide encompassed by the claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The guidelines of the Examination of Patent Applications Under the 35 U.S.C. 112 § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying

characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Fri. January 5, 2001, see especially page 1106, column 3).

The antigenic peptide of the instant claims is drawn to any peptide that is obtained from any amyloid protein. The specification of the instant application discloses some peptides (as in claim 25) that are derived from A $\beta$  amyloid. However, the claimed peptide is not limited to A $\beta$  amyloid but encompasses any amyloid proteins. It is noted that amyloid is defined as any complex protein that is deposited in tissues and shares selected laboratory features such as a change in the fluorescence intensity of certain aromatic dyes (Medicine Net definition, 8/8/04) and there are number of other amyloids does not have any structural relationship with A $\beta$  amyloid (wikipedia, 2009, p. 1-6). Given that the broad range of peptides is claimed, it is apparent that the instant specification fails to disclose any species of peptides that are non A $\beta$  amyloid. Thus, the failure of disclosure is not sufficiently representative of the broad genus of structurally different antigenic peptides other than A $\beta$  amyloid sequences of claim 25.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 19, 20 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicolau et al. (PNAS, 2002 vol. 99, no. 4, p. 2332-2337, IDS reference).

Nicolau et al. teach administration of antigenic composition comprising a peptide comprising the claimed SEQ ID NO:1 in a reconstituted liposome comprising phospholipids and cholesterol (Fig.1, p. 2333) in PBS (e.g. pharmaceutical carrier). Further, Nicolau et al. teach that a hydrophobic (e.g. palmitoylic acid) tail is attached to a lysine residue of the peptide (Introduction, p. 2332) and the peptide is derived from A $\beta$  amyloid sequence.

Given that the identical antigenic composition is administered to a group of subject having A $\beta$  plaques (p. 2333, col. 2), the referenced composition inherently treats Alzheimer's diseases by inherently enhancing antigenicity. Even if the claimed method does not recite a particular patient population, the patient population having A $\beta$  plaques cannot be excluded from the study because having A $\beta$  plaques is considered as indication of Alzheimer's disease (p. 2332). Thus, prior art population and the potential population of the claimed method are considered identical. Therefore, the reference teachings anticipate the claimed invention.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim

Patent Examiner

Technology Center 1600

August 4, 2009

/Michael Szperka/

Primary Examiner, Art Unit 1644